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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/717,379 | 11/19/2003 | Bruce M. Frankel | 7177.US.01 | 6700 |

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/04/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/717,379 | Applicant(s) FRANKEL ET AL. | |
| | Examiner Anu Ramana | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21-27 is/are rejected.
- 7) ☒ Claim(s) 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/19/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 5, 2006 has been entered.

Claim Objections

Claims 24-29 are objected to because of the following informalities. It appears that claims 24-29 should depend from claim 23 rather than claim 22. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-7 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Melker et al. (US 5,484,442).

Melker et al. disclose a threaded needle or "bone tap" having an axial passageway 31, one or more openings or "fenestrations" 34, and threads shaped or "configured" to ensure that the needle is stable and prevents leakage once inserted (Figs. 1 and 8, col. 3, lines 27-67, col. 4, lines 1-48, col. 5 and col. 6, lines 1-8).

Regarding claim 21 it is noted that Applicant is merely modifying functional recitation in claim 1. It is noted that a claim containing a "recitation with respect to the

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manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Claims 1-2, 4-8, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathis et al. (US 6,048,343).

Mathis et al. disclose a system for forming an opening in bone including a screw or "tap" 100 with a plurality of openings or fenestrations 122 spaced at regular intervals along the shaft, a head 112 with a suitably shaped opening to receive a tool or driver such as an Allen-type wrench, an adapter or "fluid port" 142 and a fluid delivery system such as a syringe with cement (col. 2, lines 29-67 and col. 3, lines 1-34).

Regarding claim 21 it is noted that Applicant is merely modifying functional recitation in claim 1. It is noted that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Karpman et al. (US 6,214,012).

Karpman et al. disclose a method of introducing bone cement or "fluid" or "bone filler" into bone including the steps of: advancing a screw or bone tap 30 into a bore 50 in bone utilizing a driver; attaching a syringe or fluid delivery device to the bone tap 30; and introducing bone cement into the bone by injecting cement into the bone tap 30 via openings 31, 40 and 42 in bone tap 30 (Figs. 3-4, 6, 9, 8A, 15, 15A, col. 7, lines 5-67, col. 8, lines 1-53, col. 9, lines 23-55, col. 13, lines 11-67, col. 14, col. 15, lines 22-67 and col. 16, lines 1-43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melker et al. (US 5,484,442) in view of Stednitz (US 4,537,185).

Melker et al. disclose all elements of the claimed invention except for at least one flute in the threads.

Stednitz teaches making a threaded body self-tapping by providing at least two flutes on the shaft of the threaded body (Fig. 3 and col. 2, lines 40-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided flutes on the threaded shaft of the Melker et al. device, as taught by Stednitz, to make the device self-tapping.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (US 6,048,343) in view of Stednitz (US 4,537,185).

Mathis et al. disclose all elements of the claimed invention except for at least one flute in the threads.

Stednitz teaches making a threaded body self-tapping by providing at least two flutes on the shaft of the threaded body (Fig. 3 and col. 2, lines 40-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided flutes on the threaded shaft of the Mathis et al. device, as taught by Stednitz, to make the device self-tapping.

Claims 9-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (US 6,048,343) in view of Simonson (US 6,159,179).

Mathis et al. disclose all elements of the claimed invention except for at least one dilator. See previous discussion of Mathis et al.

Simonson teaches using a cannula or dilator to perform a surgical procedure to limit tissue disruption and for a small incision (col. 1, lines 17-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a dilator, as taught by Simonson, in the system of Mathis et al., to limit tissue disruption.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (US 6,048,343) and Simonson (US 6,159,179), as applied to claim 9, further in view of Heini (US 4,903,691).

The combination of Mathis et al. and Simonson disclose all elements of the claimed invention except for a driver having a resilient member.

Heini teaches a driver having a resilient tab or collet 11 that is used to engage a screw head in order to drive the screw in a safe and efficient manner (Fig. 6 and col. 9, lines 14-68).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a driver, as taught by Heini, to drive the screw in the system of the combination of Mathis et al. and Simonson, in a safe and efficient manner.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karpman et al. (US 6,214,012) in view of Tague et al. (US 6,599,293).

Karpman et al. disclose all elements of the claimed invention except for providing a medicament or drug in the bone cement.

It is well known to mix antibiotics or other desired drugs in bone cement so that when the bone cement is applied to a specific surgical site, the drugs leach out and are delivered directly to the surgical site as demonstrated by Tague et al. (col. 1, lines 32-37).

Accordingly it would have been obvious to have mixed a desired drug into the bone cement prior to delivery of the bone cement utilizing the method of Karpman et al. since it was well known in the art to mix a specific drug in bone cement prior to delivery.

of the bone cement to a specific surgical site so that the drug is delivered directly to the surgical site.

The method steps of claim 25 are rendered obvious by the above discussion.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on October 5, 2006 have been fully considered but are not persuasive for the following reasons.

Regarding the limitation, "for introducing bone filler into a bone," and "configured to introduce bone filler into the bone," and "facilitates insertion of the body into bone" it is noted that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Melker et al. and Mathis et al. clearly disclose Applicants' claimed invention as discussed in the rejections above.

Allowable Subject Matter

Claims 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if the objections made in this office action are overcome.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

December 21, 2006

A handwritten signature in black ink, reading "Annadha Ramana". The signature is written in a cursive, flowing style. The first name "Annadha" is written with a large, prominent 'A' and the last name "Ramana" follows in a similar cursive script.